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## CORRECTED NOTICE OF ALLOWANCE AND FEE(S) DUE

84331 7590 12/01/2009

Baker Donelson Bearman, Caldwell & Berkowitz, PC  
555 Eleventh Street, NW, Sixth Floor  
Washington, DC 20004

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/01/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,636	02/02/1999	ELLEN M. HEATH	2902162-015000	8977

TITLE OF INVENTION: PROCESSES FOR ISOLATING, AMPLIFYING AND CHARACTERIZING DNA

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$0	\$755	02/16/2010

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. NEITHER A NOTICE OF ALLOWANCE NOR A CORRECTED NOTICE OF ALLOWANCE IS A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND ANY PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THE THREE MONTH PERIOD BEGINNING ON THE MAILING DATE OF THE PREVIOUSLY-MAILED NOTICE OF ALLOWANCE AND ENDING ON THE DATE DUE SHOWN ON THIS FORM, OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. MAILING OF THIS CORRECTED NOTICE OF ALLOWANCE DOES NOT CHANGE THE DATE DUE OF THE ISSUE FEE (AND ANY REQUIRED PUBLICATION FEE). IF A REPLY (WITH PAYMENT OF THE ISSUE FEE AND ANY PUBLICATION FEE) WAS FILED IN RESPONSE TO THE PREVIOUSLY-MAILED NOTICE OF ALLOWANCE, THEN NO FURTHER REPLY IS REQUIRED FROM APPLICANT.**

All communications regarding this application must include the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE, unless advised to the contrary.



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DATE MAILED: 12/01/2009

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/241,636	HEATH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JEANINE A. GOLDBERG	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/17/09; 8/26/09; 11/6/09.
2. ☒ The allowed claim(s) is/are 63, 66-93, 100-111.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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### **DETAILED ACTION**

1. This action is in response to the papers filed July 17, 2009, August 26, 2009 and November 6, 2009. Currently, claims 63, 66-93, 100-111 are pending.

### **REASONS FOR ALLOWANCE**

2. The following is an examiner's statement of reasons for allowance.

The claims are drawn to a method for characterizing DNA by isolating nucleic acids by lysing a cell with a solid support having dried thereon a lysing reagent and a RNA digesting enzyme, treating the biological material with a DNA purifying agent and characterizing DNA. The claim requires the lysing reagent consists of a detergent and optionally water, optionally buffer and optionally a chelating agent

The prior art teaches numerous lysing reagents. For example, Dean et al. (Am. J. Hum. Genet. Vol. 55, pages 788-808, 1994) teaches a lysing reagent comprising 20 mM Tris pH 8.0, 1% SDS, RNase A. The lysing reagent is incubated for 10 minutes followed by proteinase K treatment.

The prior art teaches treating and drying lysing reagents on a solid support. Shieh teaches preparing a lysing component by treating the membranes with a lysing agent (col. 10, lines 65-67). Similarly, Harvey specifically teaches fabricating an absorbent material with a roll of 903 paper which is impregnated with guanidine thiocyanate solution having a concentration between 0.5M and 5.0 M. The paper is allowed to dry (col. 5, lines 10-22).

Art Unit: 1634

Dr. Dirk Loeffert has filed a declaration that at the time the invention was made, one of ordinary skill in the art would not have expected a system comprising a detergent and a RNA digesting enzyme dried to a solid support to work because it was unexpected that an RNase enzyme would maintain activity when dried with a detergent. Dr. Loeffert provided objective evidence that SDS is an efficient anti-RNase detergent. The art similarly supports the chemical denaturation of RNase A mediated by SDS.

In an interview with applicant, applicant provided numerous technical reasons why, despite the teaching of a lysing reagent comprising SDS and RNAase, the ordinary artisan would not have been expected the lysing reagent to be combinable with teachings of drying lysing reagents on a solid support and maintain the desired function of the elements when dried on a solid support.

Thus, the claimed invention is not taught or suggested by the art and are allowable.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, can be reached on (571)272-0731.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

**/Jeanine Goldberg/**

**Primary Examiner**

December 1, 2009